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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,869

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EXAMINER

WIEST, PHILIP R

ART UNIT

PAPER NUMBER

3761

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/791,869	<b>Applicant(s)</b> JANSEN ET AL.	
	<b>Examiner</b> Phil Wiest	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

In the reply filed 7/2/08, applicant amended claim 12. Claims 12-34 are currently pending.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 12-19, 21, 24-29, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Niedospial (US 5,895,383).
2. With respect to Claim 12-14, 16, 21, and 34, Niedospial teaches a fluid transfer device comprising a lid portion 102 and an edge portion 104 connected to the lid portion, the lid and edge portions forming a receiving cap that is symmetrical about a central longitudinal axis and defines a space configured to receive the bead of a medical vial that is closed by an elastic stopper. The edge portion 104 is configured to center the bead within the space when the bead is disposed in the space. Niedospial further teaches a piercing mandrel connected to the lid portion and projecting into the space, wherein the piercing mandrel includes a piercing portion 116 configured to pierce the elastic stopper while the bead is disposed in the space. The piercing mandrel further includes a sealing portion (section 113 and surrounding areas) formed integrally

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with the lid portion (see the cross section Figure 6) that contacts the piercing portion and has a diameter greater than the piercing portion 116, the sealing portion being configured to contact the elastic stopper (@ section 69) when the bead is substantially disposed in the space. The diameter of the piercing mandrel is stepped as it transitions from piercing portion to sealing portion. Additionally, the piercing portion and sealing portions of the piercing mandrel are substantially conically shaped, such that they widen toward the top of the mandrel. When the bead of a vial is substantially disposed in the space, the distance between the base of the sealing portion and the distal end of the sealing portion is greater than the length between the base of the sealing portion and the external surface of the elastic stopper within the container (i.e. the sealing portion extends downward into the elastic stopper). The piercing member has a flow channel therethrough that is configured to convey fluid away from the container.

3. With respect to Claims 15 and 19, the sealing portion comprises an end face having an integral sealing element that is configured such that can form an annular interface with the elastic stopper when the bead is disposed in the space. The end face has an integral sealing element that prevents fluid from flowing through the stopper around the outsides of the piercing mandrel.

4. With respect to Claims 17, 18, 27, and 29, Niedospial teaches that the edge portion includes an inward projection (84, 120) that engages the behind portion of the bead when the bead is disposed in the space. The adapter is arranged such that the distance between the inward projection and the sealing portion is less than the distance between the inward projection and the top surface of the elastic stopper (i.e. the sealing

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portion extends downward into the elastic stopper). Because the lid portion is capable of being moved up and down, the piercing portion is configured such that it is capable of contacting the elastic stopper at the same time as the inward projection is engaged behind the bead (see Figure 8). Additionally, the vertical distance between the piercing portion 116 and the lid portion 102 is greater than the vertical distance between the piercing portion 116 and the inward projection (84, 120).

5. With respect to Claims 24 and 25, the piercing mandrel is formed integrally with and passes through the top of the lid portion (see figure 6). Therefore, the piercing mandrel is embedded in the lid portion. The mandrel is stationary with respect to the lid portion.

6. With respect to Claims 26 and 28, the inward projection is disposed radially around the piercing mandrel. The sealing portion of the piercing mandrel is configured such that it is able to penetrate the elastic stopper while the bead is being substantially disposed in the space.

7. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Wadsworth, Jr. (US 5, 374, 264). Wadsworth Jr. discloses a fluid transfer device comprising a lid portion 40 and an edge portion 15 forming a receiving cap, the receiving cap defining a space configured to receive a bead of a container closed by an elastic stopper, the edge portion being configured to center the bead of a container (via angled walls 13 and ribs 32) within the space when the bead is substantially disposed within the space, and a piercing mandrel 26 connected to the lid portion and projecting into the space. The

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piercing mandrel 26 includes a piercing portion 23 configured to pierce the elastic stopper while the bead is being disposed in the space. The mandrel further comprises a sealing portion 24 having a diameter greater than the mandrel, the sealing portion being configured to contact the elastic stopper when the bead is substantially disposed in the space (see figure 4), and a flow channel being configured to convey fluid away from the container.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niedospial in view of Meyer (US 5,358,501). Niedospial teaches claims 12, 15, and 19 (see rejection above), but does not teach the use of an o-ring sealing means around the end face. Niedospial discloses a round opening between the edge portion and the sealing portion and a flat end space contacting the elastic stopper, thus motivating one skilled in the art to include a seal that fits round openings. The use of o-rings for sealing means in medical devices is known in the art. Meyer discloses a storage bottle containing a constituent of a medical solution, which employs an o-ring as a sealing element between the two containers. Thus, it would be obvious to one skilled in the art to apply the o-ring of Meyer to the fluid transfer device of Niedospial because doing so

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will achieve an effective and inexpensive sealing means, thereby preventing the loss of fluid around the edges of the vial.

9. Claim 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niedo spial in view of Larson (US 3,977,555). Niedo spial teaches the device substantially as claimed, but does not specifically teach that transition between the piercing portion and the sealing portion is substantially stepless. Larson teaches a device for transferring fluids from a medical vial comprising a piercing mandrel having a piercing portion 38 and a sealing portion 66. To transfer fluids, the mandrel is pushed downward, causing the piercing portion 38 to pierce the elastic stopper 18, thus initiating fluid flow. The sealing portion 66 is tapered such that it forms a seal against the elastic stopper when the piercing mandrel is pushed downward. This function serves to create a seal against the elastic stopper and prevent the piercing mandrel from extending too far through the elastic stopper (see Column 4, Lines 1-57). Therefore, the tapered sealing portion performs substantially the same function as the stepped sealing portion taught by Niedo spial. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the piercing mandrel of Niedo spial with the tapered, conical sealing portion of Larson in order to provide an alternate means for sealing the piercing mandrel against the elastic stopper, thereby preventing fluid from leaking through the stopper on the outside of the mandrel.

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10. Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niedospial in view of Zinger et al. (US 6,558,365). Niedospial discloses the device of Claims 12 and 17 substantially as claimed (see rejection above), but does not specifically disclose that the edge portion further comprises a free edge extending away from the inward projection. Zinger et al. discloses a fluid transfer device comprising an edge portion that has an inward projection that holds the bead of a container in position and a free edge portion 26 extending away from the inward projection in a direction that is substantially parallel to the central axis (see Figure 2). The free edge portion has a larger inner and outer diameter than the rest of the receiving cap 20" and therefore is capable of guiding a container such that it is centered as it is inserted onto the piercing mandrel. It is very important that the mandrel pierces the elastic stopper in the center in order to reduce the chances of the stopper tearing as well as ensure that the neck of the bottle does not impede the mandrel. Furthermore, the use of flanges such as these is well established in the art in order to properly center and secure mandrel over the stopper of a bottle (Column 4, Lines 24-33). Therefore, it would have been obvious to one skilled in the art at the time of invention to modify the fluid transfer device of Niedospial with the outwardly-extending flares of Zinger et al. in order to guide a bottle into the desired position as it is inserted.

11. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thiebault (US 2002/0121496) in view of Niedospial (US 5,895,383). Thiebault discloses a fluid transfer set comprising a lid portion (44) and an edge portion (50) forming a



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receiving cap (20). Thiebault further discloses a piercing mandrel (92) that includes a sealing portion and a piercing portion (84), which is configured to pierce the elastic stopper. The piercing mandrel is *fully capable* of piercing the elastic stopper while bead is being disposed in the space if the operator presses the piercing mandrel downward at the same time. The piercing mandrel also comprises a flow channel configured to convey fluid away from the container. Thiebault further discloses an elastic stopper (36) whose edge portion is configured to center the bead within the space, and a sealing portion (52, 82 and 86) with a greater diameter than that of the piercing portion (84). The transition between the piercing portion 84 and the sealing portion 82 is substantially stepless. The sealing portion is configured to contact the elastic stopper when the bead is substantially disposed in the space. Thiebault et al., however, does not specifically disclose that the sealing portion is formed integrally with and extending from the lid portion.

Niedospial discloses a medicament container closure having a recessed integral spike. The spike comprises a piercing portion 116 and a sealing portion (above annular groove 113) that are formed integrally with a lid portion 118. The sealing portion (above section 113) extends downward such that it creates a seal at the top of the stopper (while not extending to the bottom of the stopper), thereby preventing fluid from leaking out of the container (see Figure 8). Additionally, the width of the piercing mandrel is stepped (at section 113) as it transitions from the piercing portion to the sealing portion, as per Claims 14 and 15. When the bead of a vial is inserted into the interior space, the sealing portion contacts the top of the elastic stopper at substantially the same time as

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the inward projection engages the bead, therefore creating a seal at the exact time that the piercing portion penetrates the bottom portion of the seal. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the fluid transfer set having a cylindrical piercing member of Thiebault et al. with the use of an integral sealing member of Niedospial in order to prevent fluids from leaking through the elastic stopper around the outside of the piercing mandrel, thereby preventing leaks and ensuring the sterility of the fluid.

### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

Regarding claim 34, applicant argues that the sealing portion of Niedospial is not formed integrally with the lid portion. This argument is moot because claim 34 does not specifically state that the sealing portion is formed integrally with the lid portion (this limitation is only in claim 12). It is the examiner's opinion that one of ordinary skill in the art at the time of invention would have been motivated to combine the fluid transfer device of Thiebault with the piercing member having a sealing portion of Niedospial in order to prevent fluid from leaking through the elastic stopper during fluid transfer.

However, even if claim 34 did state that the sealing portion was formed integrally with the lid portion, the mere integration of existing parts does not constitute a patentable improvement over the prior art. See MPEP 2144.04.

Additionally, Claim 34 is nearly identical to claim 12, and therefore is not patentable over the Wadsworth patent, which is discussed thoroughly in the previous rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/  
Examiner, Art Unit 3761

//Leslie R. Deak//  
Primary Examiner, Art Unit 3761  
14 October 2008